DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

August 31, 2000

Our Reference: 2938878
Thomas T. Mukaigawa, President
Monarch Seafoods, Inc.
515 Kalihi Street
Honolulu, Hawaii 96819

WARNING LETTER

Dear Mr. Mukaigawa:

On June 1, 2000, we inspected your seafood processing facility. We conducted this inspection to determine compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your histamine forming fish, specifically marlin and tuna, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. We enclosed a copy of the FDA 483 for ready reference. Your serious HACCP violations are as follows:

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving and cold storage critical control points (CCPs), to control the food safety hazard of histamine formation listed in your HACCP plan for histamine forming species of fish.

2. You must have sanitation control records that document monitoring and corrections during processing, to comply with 21 CFR 123.11(c). However, your

3. firm did not maintain sanitation control records as evidenced by the date of the last sanitation record maintained by your firm dated 9/29.

Further district review of your HACCP plan for histamine forming species of fish revealed the following deficiency:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). However, your firm's HACCP plan for scombroid species does not identify a critical limit at the receiving CCP that is adequate to control the hazard of histamine formation as a result of temperature abuse during transport. Examples of adequate critical limits at receipt for your HACCP plan might include either: (a) presence of adequate ice or other cooling agent at time of delivery; or (b) the shipment is accompanied by transportation records showing that the fish was held at or below 40° F throughout transit.

2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for histamine species of fish at the receiving and cold storage CCPs to control histamine formation is inadequate. For fish that exceeded the internal temperature of 40°F with total time/exposure above four (4) hours, unless the lot is rejected, it should be tested for histamine.

We observed similar deficiencies during the previous inspection of your facility on July 22 and 23, 1998. We discussed these deficiencies with you at the conclusion of the inspection and also reported them by correspondence to you from this office on August 14, 1998. Our recent inspection showed that your firm did not correct all of the deficiencies cited in our previous letter.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure and/or injunction.

Please advise us in writing, within fifteen working days of receipt of this letter, of the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your

response to Ms Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,

Charles D. Moss
Acting District Director
San Francisco District

Enclosure